

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference PCA30111/PSC		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/KR2003/001065	International filing date (day/month/year) 30 MAY 2003 (30.05.2003)	Priority date (day/month/year) 04 SEPTEMBER 2002 (04.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC7 A61K 9/127		
Applicant POSTECH FOUNDATION et al		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 3 sheets, including this cover sheet.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

- This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 06 APRIL 2004 (06.04.2004)	Date of completion of this report 30 NOVEMBER 2004 (30.11.2004)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer Yoon, Kyung Ae Telephone No. 82-42-481-5605 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/001065

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION

International application No.

PCT/KR2003/001065

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-14	YES
	Claims	none	NO
Inventive step (IS)	Claims	1-14	YES
	Claims	none	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims	none	NO

2. Citations and explanations (Rule 70.7)

The present invention relates to a micelle composition for drug delivery system comprising amphiphilic block copolymer, which has at least one hydrophilic block and one hydrophobic block carrying 1-30 functional group selected from the group consisting of carboxyl, amine, hydroxyl, amide, thiol and sulfonic acid group.

The following documents have been considered for the purpose of this report:

D1 = WO 2001-87354 A1 (22. 11. 2001)

D2 = EP 583955 A2 (23. 02. 1994)

D1 relates to a stable polymeric micelle-type composition containing a hydrophobic drug and amphiphilic block copolymer.

D2 relates to a polymeric micelle-type drug composition which comprises a hydrophobic drug physically trapped in a drug carrier comprising a block copolymer.

1. Novelty and Inventive Step

Compared with the present invention, none of the above mentioned prior art documents disclose that one hydrophobic block carrying 1-30 functional group is used to improve drug-loading into a micelle composition. There is no suggestion in any of the documents, either alone or in combination, which would lead to the solution posed by the present invention. Moreover, the applicants have supplied data showing that the micelle-type drug composition according to the present invention has improved drug-loading and sustained release characteristics compared to the comparative preparation (Table 2). As a consequence, claims 1-14 meet the criteria set out in PCT Article 33(2)-(3).

2. Industrial Applicability

The subject matter of claims 1-14 appears to be industrially applicable under PCT Article 33(4).